recites "Use of a papaya mosaic virus as an adjuvant". Applicant believes, therefore, that the Examiner intended to indicate that Group V is related to a method of using papaya mosaic virus as an adjuvant and has addressed the following remarks accordingly. Applicant asserts that new claims 20-42 are drawn to a method of using papaya mosaic virus, or a virus-like particle derived therefrom, as an adjuvant and, therefore, should be examined with elected Group V.

REMARKS

Claims 1-19 are currently pending and stand restricted under 35 U.S.C. §121 into the following five groups as defined in the Office Action:

I. Claims 1-11, 13, 15 and 16, drawn to an immunogen carrier complex having an immunopotentiating property, consisting of a VLP carrying at least one fusion protein, wherein said VLP is derived from a papaya mosaic virus, classified in class 424, subclass 192.1.

II. Claims 12 and 14, drawn to a method of immunopotentiating an immune response in a mammal consisting of administering a VLP with an immunogen fused to a protein of the VLP, wherein said VLP is derived from a papaya mosaic virus, classified in class 424, subclass 192.1.

III. Claims 12, 14 and 18, drawn to a method of immunopotentiating an immune response in a mammal consisting of administering a VLP with an antigen, wherein the VLP and antigen are not linked, classified in class 424, subclass 202.1

IV. Claim 17, drawn to a composition comprising a VLP and an immunogenic protein, classified in class 424, subclass 202.1

V. Claim 19, drawn to a method of using a papaya mosaic virus as a vaccine, classified in class 435, subclass 235.1.

The Examiner alleged that the above Groups are distinct for the following reasons:

- Groups I and II are related as product and process of use but are distinct because the product of Group I can be used in a materially different process.

- Group II is unrelated to Groups III-V because the claimed subject matter is not capable of being used together and has different effects.

- Group III is unrelated to Groups I and V because Group III is not disclosed as capable of being used with Groups I and V and has a different effect to Groups I and V.

- Group IV and Group III are related as product and process of use but are distinct because the product of Group IV can be used in a materially different process than Group III.

- Group IV is unrelated to Groups I and V because the claimed subject matter is not capable of being used together and Group IV has a materially different use to Groups I and V.

- Group I is unrelated to Group V because Group I has not been disclosed as capable of being used with Group V.

The Examiner has further restricted Group I into the following immunopotentiating effects:

i. Adjuvant effect
ii. Capacity to enhance cell-mediated dependent antibody production
iii. Capacity to enhance T-cell dependent antibody production
iv. Capacity of enhancing the expression of at least one co-stimulator on macrophages
v. Capacity of enhancing the expression of at least one con-stimulator on antigen presenting cells

The Examiner alleged that these groups are unrelated because each of the immunopotentiating effects requires a different and distinct protein signal in order to be initiated and produces a unique biological and physiological response.

The Examiner further restricted Group I into the following immunogens:

vi. An allergen

vii. A viral immunogen

viii. A bacterial immunogen

ix. A parasitic immunogen

The Examiner alleged that the listed immunogens are unrelated because each member of the group has a unique physical and chemical structure and a different effect.

The Examiner further restricted Group IV into the following immunogenic proteins:

x. A bacterial protein

xi. A viral protein

xii. A parasitic protein

The Examiner alleged that the listed immunogenic proteins are unrelated because each member of the group has a unique physical and chemical structure and a different effect.

Applicant respectfully traverses the above restriction for the following reasons. The guidelines provided by MPEP § 803 clearly indicate that there are two criteria that must be met for a proper requirement for restriction between patentably distinct inventions: (A) the inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and (B) there must be a serious burden on the Examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02)[emphasis added]. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Applicant asserts that the currently pending claims all relate to a virally-based immunopotentiator, compositions comprising same and methods of using the virally-based immunopotentiator. The immunopotentiator as claimed can be in the form of a papaya mosaic virus (PapMV), a virus-like particle (VLP) or a VLP fused to an antigen. Applicant asserts that each of the PapMV, VLP and VLP-fusion represent a different embodiment of the same general inventive concept and that there is no requirement that these different embodiments be capable of being used together. Furthermore, Applicant asserts that, in contrast to the Examiner's allegation, the products and methods of Groups I-V all have the same effect, namely they all immunopotentiate an immune response to an antigen in an animal.

Moreover, with regard to the Examiner's allegation that the different immunopotentiating effects of Group I are unrelated, Applicant disagrees. It is well known in the art that many of the in vivo pathways involved in these immunopotentiating effects are interrelated. Thus, initiation of one effect can lead to the initiation of one or more other effects and immunopotentiating compounds often act by initiating more than one effect. For example, immunopotentiating compounds that act as adjuvants can enhance both the humoral (antibody production) and cellular immune responses to a specific antigen. One mechanism by which an adjuvant can enhance the immune response to a specific antigen is by enhancing the expression of co-stimulators on antigen-presenting cells (APCs), of which macrophages are a specific example.

With regard to the Examiner's allegation that the specific immunogens and immunogenic proteins of each of Groups I and IV are unrelated, Applicant disagrees. Applicant asserts that regardless of the type of immunogen/immunogenic protein used with the VLP, it is with the objective of achieving the same effect, i.e. immunopotentiation by the VLP of the immune response to the immunogen/immunogenic protein.

For the reasons set forth above, Applicant asserts that the currently pending claims do not represent independent or distinct inventions, but rather all relate to the same general inventive concept (i.e. a virally-based immunopotentiator). A search of the prior art with respect to this common inventive concept can be easily conducted and does not, therefore, represent any serious burden. Moreover, Applicant asserts that in order to perform a thorough search of claims directed to a process of using a product or a composition comprising a product, the product itself must also be searched. Accordingly, Applicant asserts that the Examiner would not be seriously burdened by searching and examining all of the currently pending claims in a single application.

In summary, Applicant asserts that the Examiner has not prima facie established that the currently pending claims meet the criteria as set forth in MPEP § 803 for proper requirement for restriction. Solely in order to expedite prosecution of the instant application, however, Applicant has withdrawn claims 1-19 without prejudice or disclaimer and submits herewith new claims 20-42, which relate to elected Group V.

CONCLUSION

In view of the foregoing, applicants respectfully request the Examiner to reconsider and withdraw the restriction requirement, and to examine all of the claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

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